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EXAMINER	
JOYCE, CATHERINE	
ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,635	AFAR ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/13/05; 3/3/05; 1/4/05; 12/13/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-41 have been canceled.

2. Claims 42-51 are pending and are under examination.

Specification

3. The specification on page 1 should be amended to reflect the status of the parent application serial number 09/547,789.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 42-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claims 42-47 and 49-51 are indefinite because it recites the phrase "stringent hybridization conditions". Stringent conditions are not defined by the claim. Although the specification recites conditions that may be defined as stringent at page 12, lines 1-14, the recitation is not limiting and thus the claims in fact read on the full range of stringent conditions. Thus, neither the claims nor the specification provides a standard for ascertaining the requisite degree of stringent conditions, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

Claim 48 is indefinite because it references itself in the recitation "the nucleic molecule of claim 48 which comprises". Thus, it is not possible to discern what is claimed in Claim 48.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 42, 45, 46, and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated nucleic acid molecule which comprises a nucleotide sequence that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto; (b) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE5; (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9; (d) comprises the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138, or comprises a nucleotide sequence complementary to the nucleotide sequence designated in paragraphs (a)-(d).

It is unclear if plasmids having the exact structural and chemical identity of plasmids p24P4C12-GTE9 are known and publicly available, or can be reproducibly isolated without undue experimentation. The p24P4C12-GTE9 plasmid is described in the specification as "containing most of the coding region of the 24P4C12 gene". Clearly, without access to the plasmid p24P4C12-GTE9, it would not be possible to practice the claimed invention. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above plasmid, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the claimed plasmids nucleic acid sequence is an unpredictable event.

Applicant's referral in the specification to the deposit of the plasmid p24P4C12-GTE9 on page 75, lines 15-20, is an insufficient assurance that all required deposits have been made and all the conditions of MPEP 608.01 (p)(c) met.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

Affidavits and declarations, such as those under 37 C.F.R. 1.131 and 37 C.F.R. 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of the deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

8. Claim 42-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule that comprises a nucleotide sequence that comprises the nucleotide sequence of SEQ ID NO:1 from nucleotide residue 6 through 2138 or that comprises, does not reasonably provide enablement for a nucleotide sequence that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2; (b) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE5; (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9; (d) comprises a full-length variant of the nucleotide sequence of SEQ ID NO:1, residues 6-2138, that hybridizes to the nucleotide sequence under stringent conditions, or comprises a nucleotide sequence complementary to the nucleotide sequence designated in paragraphs (a)-(d).

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single,

simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to an isolated nucleic acid molecule which comprises a nucleotide sequence that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2; (b) encodes a protein encoded by the cDNA contained in the plasmid designated p24P4C12-GTE5; (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9; (d) comprises the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138 or a full-length variant thereof that hybridizes to the nucleotide sequence under stringent conditions, or comprises a nucleotide sequence complementary to the nucleotide sequence designated in paragraphs (a)-(d).

The specification discloses the identification and characterization of a gene and protein termed 24P4C12, wherein the 24P4C12 gene encodes a 710 amino acid protein containing 13 transmembrane domains (page 3, lines 7-10). The specification teaches that a host-vector systems comprising a 24P4C12 polynucleotide can be used for the expression 24P4C12 proteins (page 25, line 5, thru page 26 line 21). The specification teaches that proteins encoded by the 24P4C12 gene will have a variety of uses, including generating antibodies and that antibodies may be useful in diagnostic and prognostic assays and imaging methodologies in the management of human cancer, including prostate cancer (page 26, line 22-29). The specification also teaches that the

24P4C12 polynucleotides may be useful as a diagnostic marker of metastasized prostate cancer (page 45, line, 18, thru page 46-line 2).

The teaching of the specification cannot be reasonably extrapolated to the scope of the claims because the claims are broadly drawn to any and all polynucleotides that (i) encode a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, (ii) encode a protein encoded by a cDNA contained in the plasmid designated p24P4C12-GTE5; (iii) encode a protein encoded by a cDNA contained in the plasmid designated p24P4C12-GTE9, or (iv) comprises a full-length variant of the nucleotide sequence of SEQ ID NO:1 from nucleotide residue number 6 to 2138, or any and all polynucleotides that are complementary to the above polynucleotides (i)-(iv), and applicant has not enabled all of these types of nucleotides.

In one aspect, one cannot extrapolate the teaching of the specification to the enablement of the claims because, while the specification teaches the use of polynucleotides that encode the 24P4C12 protein for the production of protein and the subsequent generation of antibodies, the specification does not teach any function for the 24P4C12 protein or that the 24P4C12 protein is differentially expressed in any cancer cells compared to control, and thus one of skill in the art would not know how to use antibodies to the 24P4C12 protein and thus the protein for generating the antibodies. The teaching in the specification that an mRNA encoding 24P4C12 protein is differentially expressed in prostate cancer cells compared to normal control is not sufficient to establish that the 24P4C12 polypeptide is differentially expressed in prostate cancer cells. The prior art is replete with examples in which expression levels of mRNA are not correlated with expression levels of the encoded protein. For example, McClean and Hill (Eur J of Cancer, 1993, vol. 29A, pp.2243-2248) teach that p-glycoprotein can be overexpressed in CHO cells following exposure to radiation, without any concomitant overexpression of the p-glycoprotein mRNA. Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute

myelogenous leukemia, said patients being without mutations in the p53 gene. Brennan et al (Journal of Autoimmunity, 1989, vol. 2 suppl., pp. 177-186) teaches that high levels of the mRNA for TNF-alpha were produced in synovial cells, but that levels of the TNF alpha protein were undetectable, and Zimmer (Cell Motility and the Cytoskeleton, 1991, vol. 20, pp. 325-337) teaches that there is no correlation between the mRNA level of calcium-modulated protein S100 alpha and levels of S100 alpha protein. Eriksson et al. (Diabetologia, 1992, vol. 35, pp. 143-147) teaches that no correlation is observed between levels of mRNA transcripts encoding the insulin-responsive glucose transporter and expression levels of the protein. Thus, the observation of expression of mRNA does not appear to be predictive of concomitant expression of protein. Thus, given the state of the art as reviewed above, data on the differential expression of mRNA encoding the 24P4C12 protein in prostate tumor cells does not allow one of skill in the art to predict that the 24P4C12 protein will be differentially expressed in tumor cells. Again, as previously set forth, the specification does not teach any function for the encoded protein and because of the lack of guidance, one of skill in the art would not know how to use the encoded polypeptide or antibodies thereto.

In a second aspect, one cannot extrapolate the teaching of the specification to the enablement of the claims because, while the specification teaches the use of polynucleotides that are complementary to SEQ ID NO:1 to detect 24P4C12 RNA, it cannot be predicted and one of skill in the art would not expect that nucleotide sequences that are complementary to all of the claimed variants of SEQ ID NO:1 or the variant polynucleotides that encode the 24P4C12 polypeptide or polypeptide variants would be useful in the detection of 24P4C12 mRNA because of limited homology to the 24P4C12 mRNA.

In a third aspect, one cannot extrapolate the teaching of the specification to the enablement of the claims because, while the specification teaches the use of polynucleotides that are complementary to SEQ ID NO:1 to detect 24P4C12 RNA, it cannot be predicted and one of skill in the art would not expect that nucleotide

sequences that are splice variants of SEQ ID NO:1 would be useful in accordance with the teaching of the specification. The unpredictability of function of splice variants is well known in the art. For example, Hirashima (Int. Arch. Allergy Immunol., 2000, Suppl 1:6-9) discloses that there are multiple isoforms of ecalectin/galectin-9 (page 8, first column second paragraph, lines 10-16), and "it cannot be excluded that each isoform exhibits different biological activity" (page 8, second column, lines 6-7). Benedict et al (J. Exp. Medicine, 2001, 193(1)89-99) specifically teach that two splice isoforms of terminal deoxynucleotidy transferase (a long form and a short form) enter the nucleus but have different activity, the long form does not catalyze nontemplated nucleotide addition but rather modulates the activity of the short form (see abstract). Jiang et al (JBC, 2003, 278(7) 4763-4769) specifically teach that the type 3 Ca2+ release channel, RyR3 exhibits strikingly different pharmacologic and functional properties depending on the tissues in which it resides. Upon examination, seven tissue specific alternatively spliced variants of RyR3 were detected. One of the variants was unable to form a functional channel but was able to suppress the activity of a different release channel. The authors conclude that tissue-specific expression of RyR3 splice variants is likely to account for some of the pharmacologic and functional heterogeneities of RyR3 (see abstract). These references serve to demonstrate that one of skill in the art cannot predict the biological activity of splice variants based on the biological activity of the wild-type protein or a single protein isoform. The specification does not provide any guidance with regard to the existence of or the expression patterns alternatively spliced variants of SEQ ID NO:1. Thus, the specification does not teach nucleic acid molecules that correspond to alternatively spliced variants of SEQ ID NO:1 and provides no working examples which would provide guidance to one skilled in the art on how to use such nucleic acid molecules.

Therefore, in view of the speculative nature of the invention, the lack of predictability of the prior art, the breadth of the claims and the absence of working examples, it would require undue experimentation to practice the invention as claimed.

7. Claims 42-51 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 42-51 are drawn isolated nucleic acid molecules which comprises a nucleotide sequence that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2; (b) encodes a protein encoded by the cDNA contained in the plasmid designated p24P4C12-GTE5; (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9; or (d) comprises the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138 or a full length variant thereof, or comprises a nucleotide sequence complementary that is the complement of the nucleotide sequence designated in paragraphs (a)-(d).

Drawn to the DNA arts, the finding in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. at 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs, and the holdings of those cases are applicable to claims 42-49 of the instant case, wherein nucleic acid molecules are claimed, and to claim 50, wherein a recombinant host cell comprising the nucleic acid molecule is claimed. The holdings of those cases are also applicable to claim 51, wherein a method of producing a protein is claimed. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the claimed genus of nucleic acid molecules that (a) encodes a protein comprising the

amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2; (b) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE5; (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9; or (d) comprises a full length variant of the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138, or comprises a nucleotide sequence complementary that is the complement of the nucleotide sequence designated in paragraphs (a)-(d), per Lilly by structurally describing a representative number of species within the claimed genus or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the claimed genus in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any nucleic molecule in the claimed genus other than SEQ ID NO:1, nor does the specification provide any partial structure of the claimed genus of nucleic acid molecules, nor any physical or chemical characteristics of the claimed genus of nucleic acid molecules, nor any functional characteristics coupled with a known or disclosed correlation between structure and function for the claimed genus of nucleic acid molecules, other than SEQ ID NO:1. Although the specification discloses a single nucleic acid molecule in SEQ ID NO:1, this does not provide a description of the claimed genus of nucleic acid molecules that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2, (b) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE5, (c) encodes a protein

encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9, or (d) comprises a full length variant of the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138, or comprises a nucleotide sequence complementary to the nucleotide sequence designated in paragraphs (a)-(d) that would satisfy the standard set out in Enzo.

The specification also fails to describe the claimed genus of nucleic acid molecules by the test set out in Lilly. The specification describes only a single nucleic acid molecule wherein it describes the nucleic acid molecule having SEQ ID NO:1. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the claimed genus of nucleic acid molecules that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2, (b) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE5, (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9, or (d) comprises a full length variant of the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138, or comprises a nucleotide sequence complementary to the nucleotide sequence designated in paragraphs (a)-(d).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 42-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals, 1994 Catalog, p. 93.

It is noted that since the specification does not define the phrase "complementary to" or "a complement", it is assumed for examination purposes that a complement is any complement of the claimed polynucleotides, either a partial or a complete complement.

Claims 42-48 are drawn isolated nucleic acid molecules which comprises a nucleotide sequence that (a) encodes a protein comprising the amino acid sequence of SEQ ID NO:2 or a variant thereof at least 90% identical thereto, which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2; (b) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE5; (c) encodes a protein encoded by the by a cDNA contained in the plasmid designated p24P4C12-GTE9; or (d) comprises the nucleotide sequence of SEQ ID NO:1 from residues 6 through 2138 or a full-length variant thereof that hybridizes to the nucleotide sequence under stringent conditions, or comprises a nucleotide sequence complementary to the nucleotide sequence designated in paragraphs (a)-(d).

The Boehringer Mannheim teaches a kit comprising random primers that encompass all possible 6-nucleotide sequences (see page 93, Catalog No. 1034 731/1006 924). A subset of these sixmers will all be complements of the nucleotides specified in claims 42-48, and thus all of the limitations of the claims are met. The rejection can be obviated by amending the claims to recite, for example, "the complete complement".

10. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine Joyce
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER